

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY)	MDL NO. 1456
AVERAGE WHOLESALE PRICE)	
LITIGATION)	CIVIL ACTION: 01-CV-12257-PBS
)	Subcategory Docket: 07-CV-11618-PBS
)	
THIS DOCUMENT RELATES TO)	Judge Patti B. Saris
)	
<i>U.S. ex rel. Ven-A-Care of the Florida Keys,</i>)	Magistrate Judge Marianne B. Bowler
<i>Inc. v. Abbott Laboratories, Inc., et al., No.</i>)	
07-CV-11618-PBS)	
)	

**ABBOTT LABORATORIES INC.'S MEMORANDUM IN SUPPORT
OF ITS MOTION *IN LIMINE* TO EXCLUDE OPINIONS
PROFFERED BY PLAINTIFF'S EXPERT MARK G. DUGGAN, PH.D**

Dated: August 28, 2009

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PRELIMINARY STATEMENT

In this False Claims Act (“FCA”) case, Ven-A-Care seeks recovery of the “federal share” of alleged “excessive reimbursements” for seventeen formulations (43 National Drug Codes) (“NDCs”) of the Abbott oral antibiotic Erythromycin (the “Subject NDCs”). (Compl. ¶¶ 3, 33.) Ven-A-Care’s action seeks recovery related to payments made by nearly every state Medicaid program from 1994 to the present. (*Id.*) The United States has declined to intervene.

Ven-A-Care’s Complaint advances its now-familiar – but factually unsupported – theory of fraud: Abbott’s sales prices were lower than compendia-reported prices (AWP, WAC, and Direct Price), and Abbott allegedly marketed the “spread” to increase its sales and profits. (*Id.*) Ven-A-Care further contends that the compendia prices at issue “directly affected” and “directly influenced” the “reimbursement amounts paid the Medicaid program” for the Subject NDCs, in that “the reimbursement amount was determined from the false pricing information provided by Abbott.” (*Id.* ¶¶ 37, 39, 58.)

The factual record, including the report of Ven-A-Care’s own expert, Dr. Mark G. Duggan, belies Ven-A-Care’s contentions. Erythromycin has been a generic drug since the mid-1980s. Nearly all of the Subject NDCs were subject to CMS-established FULs or state MACs throughout the relevant time period. While Ven-A-Care alleges “spreads” exceeding 100% when all is said and done its expert’s flawed computation shows an aggregate “difference” between Medicaid payments and those average transaction prices of about 25% – just \$3 per prescription. (SOF ¶ 100.)¹ In short, rarely did the compendia prices for the Subject NDCs “directly affect” Medicaid payments or cause “excessive reimbursements,” and there was no motive for Abbott to manipulate prices to increase its market share.

¹ Citations to the Local Rule 56.1 Statement of Undisputed Material Facts Supporting Abbott Laboratories Inc.’s Motion for Partial Summary Judgment filed, contemporaneously and incorporated herein, are cited as “SOF.”

Instead of accepting this reality, Ven-A-Care advances a damage theory, through Dr. Duggan, that seeks to escape the fact that compendia prices rarely served as the basis for Medicaid payments. This motion seeks to exclude Dr. Duggan's opinions for two reasons. *First*, in order to compute damages consistent with Ven-A-Care's theory of fraud and the Court's prior precedent, Duggan needed to determine how the allegedly false prices at issue *actually impacted* each of the states' Medicaid payments on the Subject NDCs. This Court has consistently ruled in AWP litigation that, to recover damages for claims involving generic drugs, plaintiffs must show that the claims were actually paid based on a published price. *See, e.g., In re Pharm. Indus. Avg. Wholesale Price Litig.*, 478 F. Supp. 2d 164, 180 (D. Mass. 2007) (dismissing complaint "as it relates to the drugs reimbursed on a [California] MAIC methodology" because there was no causal link between the MAIC prices and the allegedly false prices reported by defendants).

Duggan made no effort to determine how Abbott's reported prices *actually impacted* Medicaid payments. Rather, most of Duggan's "damage" computation is simply the mathematical "difference" between some policy-determined state MAC level, a CMS-established FUL, or a U&C charge, on one hand, and his "corrected" prices, on the other. For example, because Texas had a MAC for NDC 00074374816 in 1996, quarter 1, Ven-A-Care's per-unit "damage" for that quarter is the \$3.23 "difference" Duggan calculates between that MAC amount (\$19.56) and 89.51% (Texas's EAC formula) of Duggan's "correct" AWP (\$16.33). Because his analysis makes no effort to quantify the actual impact, if any, that Abbott's reported prices had on the Medicaid payments of *any state*, it is of no use to the fact-finder and should be excluded in its entirety. The Court should reject Ven-A-Care's thinly-veiled attempt to revive claims not reimbursed on the basis of compendia prices – such as claims paid on the basis of a state MAC – through expert testimony inconsistent with the Court's prior holdings.

Second, more than half of Duggan’s damage computation is based on an unsupported and unreliable “extrapolation” methodology. Duggan used actual claims data to arrive at his computations for only 15 of the 49 states at issue. Even for those 15 states, the data is incomplete – missing years of necessary data.² Duggan used the data he had to “fill the gaps” in the data for the 15 states, and to manufacture a “difference” figure for 34 states where he did not rely upon any actual claims data.

Duggan admits, as he must, that his extrapolation methodology is not based on a valid, random, and representative sample of all the allegedly false claims at issue. Rather, Duggan’s extrapolation employs a sample of convenience comprised of what Ven-A-Care’s lawyers and consultants gave to him. Duggan’s extrapolations do not adhere to the guidelines provided by the courts, and even CMS, for the use of extrapolation. Not surprisingly, given the significant variability in how the states reimbursed for generic drugs like Erythromycin, Duggan’s extrapolation leads to absurd results, namely, providers being reimbursed less than their acquisition cost. (*See infra* at 17.)

Accordingly, Abbott requests an order ruling inadmissible, pursuant to *Daubert* and its progeny, Duggan’s proffered testimony on damages, or “difference.”³

DUGGAN’S “DIFFERENCE” MODEL

To prove “actual damages,” Plaintiff relies exclusively upon Duggan, a Professor of Economics at the University of Maryland. The AWP cases mark Duggan’s first foray into the

² The chart attached as Exhibit A depicts, by state and quarter, the claims data Duggan did and did not rely upon. Duggan ignored claims data produced ten additional states, the vast majority of which employed state MACs.

³ Abbott files this motion now because exclusion of Duggan’s opinions provides another reason to grant certain aspects of Abbott’s Motion for Summary Judgment, filed contemporaneously. Other than Duggan, Plaintiff has no evidence to prove causation and damages, requiring summary judgment in Abbott’s favor. *See, e.g., Albert v. Warner-Lambert Co.*, 234 F. Supp. 2d 101, 106-07 (D. Mass. 2002) (excluding expert testimony on damages and granting defendant’s motion for summary judgment); *Dunn v. Sandoz Pharm. Corp.*, 275 F. Supp. 2d 672, 684 (M.D.N.C. 2003).

“damages expert” world. (SOF ¶ 98.)

In his report, Duggan claims to have calculated a \$15,559,108 “difference”:

between (1) what the federal government reimbursed for certain pharmaceutical products [the Subject NDCs] dispensed to Medicaid recipients during 1994Q1 to 2008Q1 period and (2) what the federal government would have reimbursed for the same products during the same time period if prices reflective of the actual prices at which Abbott was transacting business had been used for the AWP, WAC, and Direct Price of Abbott products.

(*Id.* ¶ 102.) Interestingly, while Plaintiffs offer Duggan to establish actual damages, Duggan himself has repeatedly refused to describe his computations in AWP litigation as damages. Instead, he uses the term “difference.” (*Id.* ¶ 104.) And rightly so. His opinion reflects an abstract mathematical subtraction, not damages.

A. What Duggan Did.

While Duggan calculated a “difference” for each Medicaid claim, his methodology depended upon what state the claim came from. Regardless of where the claim came from, however, one thing was constant: Duggan did nothing to determine whether the Medicaid payment was actually based, in any way, on Abbott’s reported prices. (*Id.* ¶ 112.)

1. States And Periods With Some Data.

For 15 states, Duggan reviewed a patchwork of claims data covering some part of the alleged damages period (1994-2008).⁴ To make his “difference” calculation for these claims, Duggan first determined the “but for” price that he felt the states should have paid absent Abbott’s alleged fraud, by assigning what he considered to be “correct” AWP, WACs, and DPs for each of the 43 NDCs at issue and for each quarter. (*Id.* ¶ 109.) Duggan then determined whether the state actually paid more on a given claim than his asserted “but for” price. If it did,

⁴ The 15 states are California, Florida, Georgia, Illinois, Kentucky, Louisiana, Massachusetts, Michigan, North Carolina, New Jersey, New York, Pennsylvania, Texas, Virginia, and Wisconsin. Not coincidentally, these states had relatively high spending on the Subject NDCs. (*See* Ex. A; SOF ¶ 107.)

then the overage was added to his “difference” figure. For those states and quarters where he had claims data, Duggan computed (1) a “difference” (the dollar amount by which a state’s expenditures allegedly would have decreased) and (2) a “difference ratio” (the “difference” divided by the state’s actual expenditures for that NDC/quarter).

Duggan’s “difference” approach does not examine the formulas actually used, or the actual basis of payment, for any claim. Duggan admittedly did not concern himself with that critical issue. (*Id.* ¶ 109.) He simply calculated the “difference” between what was paid and what he opines should have been paid based upon his “correct” AWP, WACs, and DPs. Accordingly, despite this Court’s clear orders to the contrary, this approach calculates a “difference” even when the claim was not, in fact, *paid* based on any compendia-reported price (AWP, WAC, or DP). Thus, Duggan’s approach yields a “difference” – which Plaintiffs seek to recover as damages – even for claims paid based on a state MAC or the FUL. (*Id.* ¶ 110.)⁵ Similarly, Duggan’s approach yields a “difference” even when a claim was paid based on a provider’s U&C charge – which, again, has no tie to any compendia price.

2. States And Periods With Missing Claims Data.

When Duggan did not have the claims data for an allegedly false claim – which was most of the time – he “extrapolated.” He did so both *within the 15 states* where he had some data (to fill gaps where data was not provided), and *across the 34 states* where he had no data at all.

Extrapolation Within States. Even for the 15 states where Duggan had some claims data, there are significant gaps. (*See* Ex. A.) For example, North Carolina produced claims data only for 25 of the 60 quarters at issue (2001-2006), while the New York claims data covers 54 of

⁵ Duggan made no effort to determine which states used MACs or FULs for the Subject NDCs or for what time periods; which claims were paid based on FULs or state MACs; or what impact any compendia-reported Abbott price had on the establishment of those MACs or FULs.

the 60 quarters at issue. (*Id.*) California did not produce any claims data after 2001. (*Id.* ¶ 105.) Duggan nonetheless calculated a “difference” for nearly every quarter for these 15 states.

To cover the missing quarters, Duggan used what he calls a “difference ratio” for the nearest quarter where he did have actual claims data. (*Id.* ¶ 107.) The “difference ratio” is Duggan’s total “difference” for an NDC divided by the state’s total expenditures for that NDC in a given quarter. For example, if Duggan’s “difference” was \$100 and the state’s total expenditure for that NDC and quarter was \$200, then the “difference ratio” would be 50%. Duggan then multiplied this “difference ratio” by the total expenditures for the missing quarters (aggregate figures that he obtained from CMS), and assigned the resulting figure as the dollar “difference” during those time periods. (*Id.*) Other than a minor scaling adjustment, Duggan’s analysis assumes, without basis, that the level of “difference” between what was paid and what Duggan speculates would have been paid would remain constant.

Extrapolation Across States. Finally, Duggan reviewed no claims data at all for the vast majority of states (34 of them). So, Duggan calculated damages for those states by resorting to another unreliable form of “extrapolation.” Duggan had to start with a “sample” for his extrapolation, so he used the 15 states discussed above. Duggan did nothing to establish that these states constitute a representative sample, or to discuss what made them appropriate for this exercise, but he used them anyway as the foundation for his extrapolation.

To compute a “difference” for these 34 states where he reviewed no evidence, Duggan first used his 15-state “sample” to derive a composite “difference ratio,” which is the percentage amount that he believes the 15 states overpaid for the Subject NDCs on a quarterly basis.⁶ (*Id.*

⁶ Only quarters where the 15 states produced data are included in calculating the composite difference ratio. (*Id.* ¶ 108.) Because of large gaps in the data, particularly early and late in the damage period, Duggan’s “difference ratio” for some quarters is based on only a small subset of the 15 states, making his broader extrapolation even less reliable. (*Id.* ¶ 105.) For 2008, Duggan has no actual claims data to review.

¶ 108.) Duggan then multiplied that composite “difference ratio” by the total dollar expenditures for the Subject NDCs in each of the 34 no-data states to arrive at a dollar value “difference” totaling more than \$5.2 million.

Once again, this academic exercise is entirely divorced from the facts. Duggan ignores the methodology actually used by the states to pay any particular claim, and he assumes without verification that all of the payments in the 34 no-data states were set on the same bases as those in the 15 “sample” states. He does not account for the prevalence of FULs and MACs in these various states. If a state had a MAC in place, the payment per claim tends to be dramatically lower than those in states that did not. The disparity in state payment amounts makes it more difficult to extrapolate reliable “differences” for those states using data derived from others. Nor does Duggan’s analysis account for the many state Medicaid programs that knowingly paid a margin on drug ingredient costs to provide a profit to providers, subsidize inadequate dispensing fees, and ensure continued access to care. (*Id.* ¶¶ 116-117.)⁷ But Duggan does not mention these facts, or attempt to account for them in his theoretical model in any way.

In total, Duggan’s Medicaid extrapolation accounts for over half (\$8,491,936) of the \$15,559,108 in Medicaid damages claimed by Plaintiff – \$3,243,628 for within-state extrapolation and \$5,244,308 for across-state extrapolation.

ARGUMENT

I. APPLICABLE STANDARDS FOR EXPERT TESTIMONY.

An expert’s testimony is not admissible where it is not “based upon sufficient facts or data,” or does not result from applying reliable principles and methods to the facts of the case.

⁷ Ironically, much of this evidence comes from the same accounting firm, Myers & Stauffer, upon which Duggan relies in his report. (*See, e.g.*, 2002 M&S report for California: “These margins on ingredient cost must be considered in tandem with an analysis of pharmacy dispensing cost and dispensing fee reimbursement in order to fully evaluate the issue of the adequacy of Medi-Cal pharmacy reimbursement.”) (*Id.* ¶ 115).)

Fed. R. Evid. 702. Methodology “is the ‘central focus of a *Daubert* inquiry,’ but the court ‘may evaluate the data offered to support an expert’s bottom-line opinions to determine if the data provides adequate support to mark the expert’s testimony as reliable.” *United States ex rel. Loughren v. UnumProvident Corp.*, 604 F. Supp. 2d 259, 264 (D. Mass. 2009) (Saris, J.) (quoting *Ruiz-Troche v. PepsiCola of P.R. Bottling Co.*, 161 F.3d 77, 81 (1st Cir. 1998)). The factors used to evaluate the admissibility of expert testimony include (1) whether the theory or technique can be and has been tested; (2) whether the technique has been subjected to peer review and publication; (3) the technique’s known or potential rate of error; (4) the existence of standards controlling the technique’s operation; and (5) the level of the theory’s or technique’s acceptance within the relevant discipline. *See Loughren*, 604 F. Supp. 2d at 264.

“The Court’s vigilant exercise of this gate-keeper role” in the admissibility of expert opinion “is critical because of the latitude given to expert witnesses to express their opinions on matters about which they have no firsthand knowledge, and because an expert’s testimony may be given greater weight by the jury due to the expert’s background and approach.” *Id.* at 265. These concerns are heightened in the FCA context, where damages are trebled.⁸ After all, “[u]nder the False Claims Act,” no less than any other context, “damages must be proven with reasonable certainty.” *United States ex rel. Ervin & Assocs., Inc. v. Hamilton Sec. Group, Inc.*, 370 F. Supp. 2d 18, 55 (D.D.C. 2005); *see also United States v. Collyer Insulated Wire Co.*, 94 F. Supp. 493, 499 (D.R.I. 1950) (damages in FCA cases cannot be the subject of “speculation and guesswork”).

⁸ *See* Breckinridge L. Wilcox & Jefferson M. Gray, *Extrapolation of Damages and Penalties in Fraud Cases: A Slippery Slope in FCA Actions*, Business Crimes Bulletin (Dec. 2000) (“[T]he FCA’s provisions for multiple damages and penalties mean that the financial impact of any claims erroneously treated as improper under the extrapolation will be greatly magnified.”); *accord Euromodas v. Zanella*, 368 F.3d 11, 17 (1st Cir. 2004) (“Antitrust liability is strong medicine (for example, it exposes a defendant to treble damages, see 15 U.S.C. § 15), and thus section 1 of the Sherman Act has been authoritatively interpreted to limit the inferences that may be drawn from ambiguous evidence.”).

II. THE COURT SHOULD EXCLUDE DUGGAN’S “DIFFERENCE” OPINION IN ITS ENTIRETY.

Duggan’s \$15,559,108 “difference” opinion is consistent with neither accepted standards nor this Court’s prior holdings. It should not be allowed to serve as the basis for a damages award, let alone treble damages, and should be excluded.

This Court has consistently ruled in AWP litigation that, to recover damages for claims involving generic drugs, plaintiffs must show that the claims were, in fact, paid based on a published price. In the California AWP litigation, the Court dismissed the complaint “as it relates to the drugs reimbursed on a MAIC methodology” because there was no causal link between the MAIC prices and the allegedly false prices reported by defendants. *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 478 F. Supp. 2d at 180. The Court dismissed claims paid on MAIC after 2002 because California – like many other states – used information from wholesalers to set their state MACs, not compendia prices. (*Id.*)

Similarly, in Track 1, the Court refused to certify a class for physician-administered generic drugs paid on the basis of MACs, without reference to AWPs, because plaintiffs failed to explain how the alleged scheme of fraud could work in such a situation. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 91 (D. Mass. 2005) (“generics will be considered only to the extent the price in the contract between the TPP and physician is expressly predicated on AWP”); *see also Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 151 (D. Mass. 2008) (noting Massachusetts also used FULs and MACs for generics and stating plaintiffs failed to show how defendants’ reported prices actually “formed the basis for the drug’s FUL and MUL”).

Here, Duggan’s analysis reveals that most of the claims for which Duggan computes a “difference” were *not* paid based on the compendia prices about which Ven-A-Care complains. While Ven-A-Care claims that Abbott’s reported prices were “two or three times the cost of the

drugs” and computes “spreads” exceeding 100% (*see* Compl. ¶ 14, Ex. A), Duggan’s aggregate “difference ratio” – the percentage Medicaid spending allegedly would have declined with Duggan’s “corrected” compendia prices – approximates only 25%.⁹ (*Id.* ¶ 113.) The reason for the disparity between Ven-A-Care’s spread allegations and Duggan’s low aggregate difference ratio is apparent: most claims were, in fact, paid on the basis of a CMS-established FUL, a state MAC or a provider U&C, not compendia prices.¹⁰ Duggan’s “difference” analysis, however, does nothing to eliminate claims reimbursed on the basis of a FUL, MAC or U&C. Nor did Duggan do anything to assess whether Abbott’s reported prices had any impact, whatsoever, on FUL or MAC pricing levels. (*Id.* ¶ 109 (Duggan report: “It is worth nothing that I have not evaluated the effect of Abbott’s published prices on the calculation of FUL or MAC prices.”).) He did not “drill down” on these issues. (*Id.* ¶ 118.)¹¹ As it stands, Duggan’s “difference” does nothing to establish or quantify a casual link between Abbott’s reported prices and these other payment levels; it is simply a subtraction exercise.

Rather than eliminate such claims, Duggan computes a “difference” on them. In fact, most of Duggan’s \$15,559,108 difference is attributable to claims that were actually paid on the basis of a FUL, MAC or U&C charge, not compendia prices. But this Court has already ruled – *in a case involving Ven-A-Care* – that claims paid on the basis of a MAC (that did not rely on

⁹ The chart attached as Exhibit B shows Duggan’s average difference fractions by NDC.

¹⁰ Duggan’s analysis confirms Abbott’s understanding, as reflected in the testimony of Abbott employee Joe Fiske, of how these drugs were reimbursed: “You have to keep in mind that the erythromycin products were multisource pharmaceuticals and often third-party payors, whether it be government agencies or others, don’t reimburse based off of an AWP. They actually reimburse based on some MAC formula.” (*Id.* ¶72.)

¹¹ The record in this case is replete with evidence showing that states did *not* rely upon compendia prices to establish their MAC pricing levels. For example, Maryland established MACs using information from either wholesalers or cooperating pharmacists. (*Id.* ¶ 89(c).) Michigan had an extensive MAC list developed by a pharmacist consultant who researched MAC prices from other states, insurers, and wholesaler catalogs, and then considered comments from pharmacists. (*Id.* ¶ 88.) Nebraska, Georgia, New Hampshire and Illinois received MAC recommendations from vendors. (*Id.* ¶ 89(a).) Washington determined MACs based on wholesaler surveys and negotiations with pharmacy providers. (*Id.*) Ohio, Arkansas and Maine set prices based on invoice prices provided by pharmacies. Minnesota set MACs based on informal retail pharmacy surveys. (*Id.* ¶ 92.)

compendia prices) are dismissed. *See* 478 F. Supp. 2d at 180. Ven-A-Care cannot put such claims back into play through expert damage testimony that is inconsistent with that holding.

Erythromycin claims paid by California provide a telling illustration. Eleven of the Erythromycin NDCs at issue here were also included in Ven-A-Care's California *qui tam* against Abbott. (SOF ¶ 129.) Because California had a MAIC for many of those NDCs (through today), those claims were dismissed by the Court's March 22, 2007 decision. *See* 478 F. Supp. 2d at 180. Duggan's "difference" opinion, should it be admitted, would serve to "un-dismiss" those same claims. This Court should reject this attempted end-around of its prior rulings.

If history is any guide, Ven-A-Care will seek to defend Duggan's flawed approach with an argument that this Court already rejected in the California litigation: Had Abbott reported lower prices, those lower prices would have formed the basis of payment for states which used a "lower-of" methodology. (*See* Dkt. No. 2181 (Cal. 3/3/06 Br.) at 34-35 ("Even after 2002, when MAICs were not set on reported prices, the reimbursement formula always paid 'the lower of' MAIC, AWP, or other prices. Had Defendants' AWP's not been falsely inflated, they would often have been lower than the MAICs and would have set the reimbursement price.").) The Court's previous rejection, 478 F.Supp. 2d at 180, of this argument was correct for several reasons. The entire premise of the alleged fraud is that Abbott reported allegedly inflated prices in order to provide a kick-back to its Customers and increase its market share. (*See* Compl. ¶¶ 3, 19-20, 59.) This theory collapses when a state does not base reimbursement on the reported price, such as when a state sets a MAC or FUL price for a generic drug. In such cases, Abbott could not increase its market share by manipulating reported prices.

Furthermore, to permit "damage" recovery attributable solely to the "difference" between MACs/FULS and Duggan's "but-for" price would overturn deliberate state and federal policies

on what payment levels were appropriate and fair under the circumstances. Had Duggan reviewed the fact record, he would have learned that CMS considered and expressly rejected basing the FUL amount on actual acquisition cost. Rather, CMS established FULs at 150% of the lowest compendia reported price for the explicit purpose of “building into our rates for ingredients a *profit margin* for pharmacists.” (*Id.* ¶ 68) (emphasis added). More recently, Congress changed the formula for setting FULs in a way designed to allow a margin of 250% above the Average Manufacturer Price. In Ven-A-Care’s hands, Duggan’s “difference” methodology turns these deliberately allowed margins into “damages.”

Likewise, extensive record evidence makes clear that state MAC pricing was influenced by policy determinations and a give-and-take with providers to come up with levels that were fair under the circumstances. (SOF ¶¶ 91.) There is no evidence that states believed their MAC levels – what they usually paid for the Subject NDCs – led to “excessive reimbursement,” as Duggan’s “difference” model presupposes. For example, South Dakota structured its MAC pricing “to insure that the profit to the pharmacist to dispense the generic product is higher than that associated with dispensing the brand product.” (*Id.* ¶ 92.) With respect to MAC pricing, Tennessee’s Leo Sullivan testified “it’s just so fundamental” that a state “would want to pay some profit on multiple-source drugs to incentivize their use.” (*Id.* ¶ 95.) Florida would “try to set the reimbursement level at a point where 95 percent of the providers could purchase the drug at or below that price,” and eventually set its MAC pricing at 250% of Average Manufacturer Price. (*Id.* ¶ 92.) Minnesota described its approach to establishing MACs as follows:

SMACs are based on an informal survey of a few retail pharmacies that have agreed to share their costs. *The State tries to include an average profit of about \$7.00 for each prescription using SMAC.* This \$7 includes the \$3.65 dispensing fee. . . .

(*Id.*) (emphasis added).

Indeed, the profit that Minnesota deliberately provided in its MAC is *more* than Duggan's \$3 average "difference" per prescription. Although Duggan admitted that it was possible that "state Medicaid programs and providers engaged in a process where they looked at proposed MAC levels, considered all the issues that might go into drug payment policy and decided on a MAC level that was fair and workable," he ignored the evidentiary record entirely. (*Id.* ¶ 116.) Thus, not only is Duggan's "difference" analysis inconsistent with the Court's prior precedent, it is meaningless as a proper assessment of damages. It should be excluded in its entirety.

III. AT A MINIMUM, THIS COURT SHOULD STRIKE THOSE PARTS OF DUGGAN'S "DIFFERENCE" OPINION THAT RELY ON EXTRAPOLATION.

The second major problem with Duggan's "difference" opinion – which the Court need not reach if it agrees with Abbott's first argument – is his reliance on a flawed and unsupported extrapolation methodology to compute damages for many of the claims at issue. Duggan's extrapolation of "differences" from 15 states (with incomplete data), to 34 others (with no data at all), suffers from the same flaws this Court identified in its recent decision in *Loughren v. UnumProvident Corp.*, 604 F. Supp. 2d 259, including a lack of support for the extrapolation approach used and a demonstrated susceptibility to absurd results.

1. The Sample.

The first and most glaring problem with Duggan's extrapolations is that he failed to begin with a valid sample. Instead of using a random sample of representative claims paid by *all of the states*, Duggan simply used the data he was given for 15 high-expenditure states.¹²

In stark contrast to common sampling and extrapolation standards, Duggan's report contains *no discussion at all* of how he chose the "sample" he uses in his extrapolation.

¹² Due to the wide variation in how states paid for the drugs at issue, Abbott has consistently maintained that a representative sample of claims in these cases would include information for each state, each NDC, and for each time period (quarter/year). (*See* Dkt. No. 5173 at 7.)

Compare Loughren, 604 F. Supp. 2d at 261 (“According to his expert report, Mercurio considered and rejected using simple random sampling, the most basic sampling procedure (the one familiar even to lawyers and judges), and stratified sampling . . .”). Unlike in *Loughren* – where the expert at least purported to follow *some* methodology (“cohort sampling”), and yet was still excluded – there is no evidence that Duggan employed *any* “sampling” methodology at all. He just took the data he was given by Ven-A-Care and ran with it. Abbott has been unable to locate any precedent in law or literature for Duggan’s “sample of convenience” approach.¹³

It is not as though Duggan had nowhere to turn for guidance. The *Reference Manual on Scientific Evidence*, commonly used by courts to evaluate statistical extrapolations, would have been a good place to start. *See id.* at 269 (citing *Reference Manual*). Duggan did not draw his sample from “the population [of] the whole class of units that are of interest” – here the universe of allegedly false claims from all states – such that any given claim had a “known, nonzero probability of being chosen.” *See* David H. Kaye & David A. Freedman, *Reference Guide to Statistics*, in *Reference Manual on Scientific Evidence* at 90, 100 (Fed. Judicial Ctr. 2d ed. 2000). Perhaps because he did not employ a standard or logical sampling method, Duggan does not even attempt to assign a margin of error, or confidence interval, to his extrapolated “difference” analysis so that the Court can evaluate the reliability of his work. “Whenever possible, an estimate should be accompanied by its standard error.” *Id.* at 117.

Nor is Duggan’s approach consistent with CMS’s instruction on statistical sampling in “overpayment” cases. In its detailed protocols for Medicare Carriers, CMS instructs the Carriers to use “statistical sampling in their reviews to calculate and project [i.e., extrapolate]

¹³ Two experts retained by Abbott, Dr. James W. Hughes (a Professor of Economics at Bates College) and Mr. Steven J. Young (an accountant with considerable healthcare consulting experience), have provided extensive testimony in their reports and depositions detailing the shortcomings of Duggan’s extrapolated “differences.” Those criticisms can be found on pages 30-33 of Dr. Hughes’s report and pages 24-27 of Mr. Young’s report. (*See* SOF 123, James W. Hughes Expert Report, Steven J. Young Expert Report.)

overpayment amounts to be recovered by recoupment, offset or otherwise.” (SOF ¶ 121.) Under the CMS protocols, Duggan would have been required, among other things, to ensure that each allegedly false claim at issue (claims *from all 49 states*) had a “known probability of selection,” or that his “universe and sampling frame . . . [included] all relevant claims for the period under review.” (*Id.*) Only claims from 15 states (and even then, only for certain time periods) had any chance of being included in Duggan’s “sample.” He did not use any of the sampling techniques – simple random sampling, systematic sampling, stratified sampling, or cluster sampling – recognized by CMS. (*See id.*) In short, Duggan’s extrapolation does not comport with the “standards controlling the technique’s operation.” *Loughren*, 604 F. Supp 2d at 264. And contrary to the CMS protocols, Duggan did not, presumably because he could not, “provide complete documentation of the sampling methodology that [he] followed.” (*Id.*).

This Court should not permit any aspect of Duggan’s “difference” computation that relies upon an unsupported and flawed extrapolation methodology to be introduced to the jury. *See United States v. Skoknek*, 933 F. Supp. 1108, 1115-18 (D. Mass. 1996) (rejecting Government’s extrapolation loss calculation used in sentencing of psychiatrist-defendant in criminal Medicare billing fraud case because the “extrapolation was not done according to the usual statistical formalities,” but instead was a “convenience sample garnered by a unit whose purpose is to investigate fraud”); *Allgood v. Gen. Motors Corp.*, No. 102CV1077, 2006 WL 2669337, at *9-11 (S.D. Ind. Sept. 18, 2006) (rejecting expert testimony when expert “failed to offer any scientific justification for his sample selection choices, which are central to the reliability of his methodology”); *Collyer*, 94 F.Supp. at 498-99; *Whipple*, 2002 WL 864246 at *12.

2. Extension Of The Sample.

Ignoring established statistical standards is only the beginning of the problem with Duggan’s extrapolations. Magnifying the problem is the known variability in how states

reimbursed for generic drugs like Erythromycin NDCs. This variability underscores the need for Duggan to either use detailed claims data (showing how the states actually paid the Subject NDCs) or construct a sample which is fairly representative of *all* of the claims at issue.

Across State Extrapolation. Duggan's extrapolation assumes that the impact of his revised "but for" prices on Medicaid spending would be the same for claims paid by the 34 no-data states as it was for the 15 states in his non-random sample. This unstated assumption presumes that the 34 extrapolated states focused on the same factors to establish ingredient payment levels as did the 15 states with data. That assumption has no merit. For example, when a state implemented a MAC for a particular drug, both *how* a state reimbursed a particular NDC and the *amount* paid changed. (*Id.* ¶¶ 87, 89.) Yet Duggan made no effort to determine which states established MACs for the Subject NDCs, or to compare the relative prevalence (or numerical values) of state MACs among the 15 and 34 state groups, respectively. (*Id.* ¶¶ 109-110.)

Duggan ignored these critical details and instead simply reviewed the basic adjudication formulas (*e.g.*, whether states used AWP, WAC, or DP) to establish comparability between the states. (*Id.* ¶ 108.) Such a simplistic approach might have worked for branded drugs, but it certainly does not work in the world of generics, where payment amounts are typically based on state MACs or FULs (not AWP, WAC, or DP). A 2004 report from OIG explains why Duggan's approach does not work for generic drugs. (*Id.* ¶ 125.) Using 2001 data, OIG found that states' payment per unit for the same drugs varied widely: "On average the highest paying State paid 477 percent more per drug than the lowest paying State for each of the 28 drugs in our sample." (*Id.*) Not surprisingly, OIG found *much greater variation in reimbursements for generic drugs*, with the median and average variations of 374% and 1230%, respectively,

between the highest and lowest paying states. (*Id.*) Even the “average difference between the State at the 25th percentile and the State the 75th percentile (*i.e.*, the interquartile range) was 63 percent for the 10 non-innovator multisource drugs.” (*Id.*) In short, OIG found that various states’ payment amounts for the same generic drugs were all over the proverbial map.

OIG believed this variability was due to differences in state MAC pricing, as well as differences in states’ definitions of “usual and customary charge” and the frequency with which drugs were reimbursed at U&C. (*Id.*) Specifically, the OIG stated: “*Even States with the same formula for estimating pharmacy acquisition demonstrated variation in their average annual reimbursement prices,*” thus undercutting the “widespread assumption . . . that states with the same estimated acquisition cost formula pay similar prices.” (*Id.* at 126) (emphasis added). To put it bluntly, OIG has *explicitly rejected* the very assumptions upon which Duggan relies to establish comparability between states.¹⁴

It is not surprising, then, that Duggan’s extrapolated “difference” calculation for the 34 no-data states leads to bizarre results. In some instances – such as when a state had an aggressive MAC – the “but-for” scenario created by Duggan suggests that the states should have

¹⁴ Duggan claims that he checked for “selection bias” by comparing the amount of Medicaid reimbursement “per claim” between his sample set and the extrapolated states. (*Id.* ¶ 107.) This comparison does not bolster Duggan’s analysis for several reasons. First, the comparison covered only the years 1999 to 2004. Second, when asked why he did not at least exclude those NDCs where the per-claim reimbursement was *lower* in the extrapolated states, Duggan himself acknowledged that many variables that could skew his per-claim reimbursement computation:

[T]here are a number of reasons why it [reimbursement being lower per claim in extrapolated states] could be true. One would be the importance of the dispensing fee may differ between two states for two pairs of drugs. So for example you may have a drug, two states, one with a dispensing fee of 5, the other with a dispensing fee of 3, and, you know, there could be something else about the formula that would differ. There are just many factors. It could be something about the dispensing fee, something about the ingredient cost reimbursement, the number of units, the price that’s being used and so forth. So there are a number of factors that could produce that.

(*Id.* ¶ 107.) In other words, Duggan admitted that his simple “per-claim reimbursement” comparison is not a reliable indicator of the relative amount states paid in ingredient cost on a per-unit basis. Third, Duggan’s check for selection bias was performed at a macro level, comparing average payment per NDC for the 34 states to the average payment per NDC for the 15 states. He did not make any comparisons on a state-by-state basis. (*Id.*)

paid absurdly low amounts for drugs. For example, for the second quarter of 2004, Maryland imposed a MAC of \$9.57 for NDC 00074632613 (250 MG Erythromycin tablets). (*Id.* ¶ 127(a)) Duggan ignored this MAC, as he does all MACs, and simply applied a composite “difference ratio” derived from his 15-state sample to the total expenditures made by Maryland to arrive at a dollar value “difference.” For the NDC-quarter (00074632613, Q2, 2004), Duggan applies a difference ratio of 19.918%. In other words, Duggan reduces the payment on claims for this NDC- quarter by nearly 20%. Applying this difference ratio to Maryland’s MAC-based payment for this product (\$9.57) would lead to a per-unit payment of just \$7.66 – below Duggan’s estimate of what providers actually paid (\$8.15) for this product. (*Id.*)¹⁵ In other words, Duggan calculated what Ven-A-Care would call “damage” where there was none. Extending this loss to all providers for this NDC reimbursed by Maryland means that pharmacies would have lost 5.9% of each reimbursement on this NDC alone for this one quarter in 2004.

Another example of these absurdly low payments amounts can be seen in Nebraska, a state that also reimbursed for erythromycin based on MAC. For the first quarter of 1997, Nebraska imposed a MAC of \$32.50 for NDC 00074632653 (250 MG Erythromycin tablets). (*Id.* ¶ 127(b).) Duggan applied a composite “difference ratio” derived from his 15-state sample to the total expenditures made by Nebraska to arrive at a dollar value “difference.” For the NDC-quarter (00074632653, Q1, 1997), Duggan applies a difference ratio of 20.727%. (*Id.* ¶ 107.) Applying this difference ratio to Nebraska’s MAC-based payment for this product (\$32.50) would lead to a per-unit payment of just \$25.76 – well below Duggan’s estimate of what providers actually paid (\$27.80) for this product. (*Id.* ¶ 118.)¹⁶ Ven-A-Care thus suggests that, if payment levels were properly set, providers should have taken a 7.3% loss on each

¹⁵ The calculation is \$9.57 minus Duggan’s payment reduction of \$1.91 (\$9.57 times .19918) = \$7.66.

¹⁶ The calculation is \$32.50 minus Duggan’s payment reduction of \$2.04 (\$32.50 times .20727) = \$25.76.

prescription of this product to a Medicaid patient. These are just two examples of the absurd results that pervade Duggan's extrapolation, yet he did nothing to evaluate, eliminate, or control for them.

At bottom, states are not homogenous when it comes to Medicaid payments for generic drugs. Because Duggan's sample does not include any claims from the 34 extrapolated states, the sample is by no means "appropriately representative of the larger entity or population being measured." *Allgood*, 2006 WL 2669337, at *11. As important, Duggan cannot even test whether his sample is representative because the data necessary to do so no longer exists. This, too, renders Duggan's extrapolation inadmissible. *See Collyer*, 94 F.Supp. at 498-99 (refusing to allow extrapolation of results from one set of contracts to another set where plaintiff could not establish that the former was appropriately representative of the latter); *Albert*, 234 F. Supp. 2d at 106 n.7 ("there is no basis whatsoever for an extrapolation from the nursing home market to the hospital market"); *Whipple*, 2002 WL 864246, at *12.

Within State Extrapolation. Duggan's extrapolation within the 15 states where he had at least some data is also unreliable. Duggan did not evaluate whether factors that directly impact how much the 15 states paid for the Subject NDCs – such as existence and dollar amounts of state MACs/FULs or the basis of payment – changed over time. (*Id.* ¶ 107.) As a result, his within state extrapolations are divorced from reality and his failure to test his theory violates the standards established in *Daubert*.

Where he had detailed data, Duggan determined the percentage of claims reimbursed on the basis of U&C. (*Id.* ¶ 118 .) Duggan's analysis shows considerable variability within a given state over time in the percentage of claims reimbursed at U&C, and a general decline across the states in the percentage of claims reimbursed on that basis. (*Id.*) For example, in Illinois, which

produced a relatively full set of data, Duggan found that the percentage of U&C-based payments declined from 30% in 1994 to 2.06% in Q1 2006. (*Id.*) Similarly, Duggan found that U&C-based payments in New York decreased from 44% in 1995 to 1.4% in Q1 2006. (*Id.*) Despite this wide variability demonstrated in states which produced substantial data across the entire time period, Duggan nevertheless assumes that the data produced for states like Georgia, Pennsylvania, North Carolina, Michigan, and Virginia later in the time period is representative of prior quarters where no data was produced. In light of the contrary experience in Illinois and New York, this is almost certainly a false assumption that leads to overstated results.¹⁷ These lapses in Duggan's analysis are critical, not to mention the fact that U&C-based payments are not related to Abbott's reported prices and should not be assigned as damages in any event. At bottom, Duggan's failure to account for this sort of variability in payment bases renders any extrapolation to other time periods for which he lacks data within a state unreliable and overstated, and the Court can have no confidence in his results.

CONCLUSION

For the foregoing reasons, the Court should enter an order excluding Duggan from offering any testimony regarding the "difference" between what Medicaid programs paid for the Subject NDCs and what they alleged "would have paid" had Abbott reported different prices.

¹⁷ Because U&C served as the basis for payment only when it was lower than EAC, claims reimbursed at charges would have a lower "difference" than claims reimbursed on the basis of EAC. Extrapolating from a period with a higher percentage of EAC-based reimbursements to a period with a lower percentage of EAC-based reimbursements would thus serve to overstate the "difference" in the extrapolated period.

Dated: August 28, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Carol P. Geisler, an attorney, hereby certify that I caused a true and correct copy of the foregoing to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 28th day of August, 2009.

/s/ Carol P. Geisler
Carol P. Geisler

EXHIBIT B**SUMMARY OF ERY "DIFFERENCE" FRACTIONS BY NDC**

NDC	Stipulated Drug List Name	Total Fed Diff	Diff Frac Summary ⁽¹⁾
			Average
00074258913	Erythromycin Ethylsuccinate Tab 400 mg	595,589	0.210491
00074258953	Erythromycin Ethylsuccinate Tab 400 mg	61,998	0.216562
00074374716	ERYTHR ETH LIQ 200mg/15ml	892,880	0.219501
00074374816	ERYTHR ETH LIQ 400mg/5ml	579,369	0.260878
00074572911	E.E.S. 400 FILM	3,400	0.064845
00074572913	E.E.S. 400 FILM	212,191	0.145105
00074572919	E.E.S. 400 FILM .	2,560	0.123878
00074572953	E.E.S. 400 FILM	49,840	0.146619
00074622713	ERYTHR BSE TAB 500mg	578,360	0.202851
00074630113	ERYTHROMYC DR 250mg CAP	574,276	0.262528
00074630153	ERYTHROMYC DR 250mg CAP	96,611	0.256632
00074630411	Ery-tab E/c Ud 250 Mg 100's	10,551	0.272607
00074630413	Ery-tab E/c 250 Mg 100's	914,565	0.288976
00074630430	Ery-tab Elc 250 Mg 30's	1,155	0.345799
00074630440	ERY-TAB 250MG E	4,286	0.324141
00074630453	ERY-TAB 250MG E	360,245	0.289148
00074630613	EES 200 Susp.100ml	3,204	0.063728
00074630616	EES 200 Liq 200 Mg/5 ml	68,961	0.121964
00074631613	Erythromycin Stearate 500 Mg Tab 100's	1,113,715	0.188908
00074632011	Ery-tab 333 mg	21,436	0.319575
00074632013	Ery-tab 333 mg	3,384,912	0.299311
00074632030	Ery-tab 333 mg	4,787	0.281639
00074632053	Ery-tab 333 mg	1,030,974	0.314135
00074632111	Ery-tab 500 Mg u	3,443	0.263358
00074632113	Ery-tab 500 Mg e	619,780	0.249768
00074632611	ERYTHR BSE TB 250mg	8,189	0.197256
00074632613	Erythromycin Base 250 Mg Tab 100's	399,530	0.192776
00074632653	Erythromycin Base 250 Mg Tab 500's	108,899	0.192442
00074634619	ERYTHR STE 250mg TAB	29,006	0.19842
00074634620	Erythromycin Stearate 250 Mg Tab 100's	505,222	0.195826
00074634638	Erythromycin Stearate Ud 250 Mg Tab 100's	3,884	0.120749
00074634641	ERYTHR STE 250mg TAB	927	0.1276
00074634653	Erythromycin Stearate 250 Mg Tab 500's	540,184	0.204832
00074636902	E.E.S. GRAN 200	3,986	0.088863
00074636910	E.E.S. GRAN 200	8,170	0.124504
00074637313	E.E.S. 400 LIQ	2,127	0.070655
00074637316	EES 400 Liq 400 Mg/5 ml	37,764	0.137356
00074715613	EES/sulfisoxazole 200 Mg, 100 ml	669,659	0.332733
00074715643	EES/sulfisaxazole 200 Mg 150 ml	987,275	0.358651

00074715653	EES/sulfisoxazole 200 Mg 200 ml	807,025	0.359027
00074803013	Pediazole Susp	58,533	0.106815
00074803043	Pediazole Susp	76,822	0.116544
00074803053	Pediazole Susp	122,810	0.149362

(1) Average exclude quarters when no diff frac is calculated by Dr. Duggan